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NEWS

Idaho Board of Pharmacy

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2006 Legislature Ends

Again this year there have been a number of changes in code and rules that will directly affect the practice of pharmacy. All of these changes are available through the Idaho Board of Pharmacy Web site. At the request from the Department of Health and Welfare the following language was struck from Rule 188 and is now in effect.

Rule 188. Drug Product Selection

01. Method of Drug Product Selection. ~~Drug product selection will be allowed for Medicaid patients unless indicated in the prescriber's own handwriting on the face of the prescription or drug order "BRAND MEDICALLY NECESSARY."~~ For non-Medicaid patients a brand must be dispensed only if the prescriber has indicated "BRAND ONLY" by checking the appropriate box on the face of the prescription.

The following Bills will take effect on July 1, 2006:

House Bill 530

House Bill No. 530 addressed the sale of pseudoephedrine.

37-3301. DEFINITIONS. As used in this chapter:

1. "Pseudoephedrine product" means any compound, mixture or preparation containing any detectable quantity of pseudoephedrine, its salts or optical isomers, or salts of optical isomers.
2. "Retailer" means any person, other than a wholesaler, who sells or offers for sale or distributes at retail pseudoephedrine products, irrespective of the quantity or the amount of sales of such pseudoephedrine.

37-3302. SALES OF PSEUDOEPHEDRINE PRODUCTS. A retailer shall ensure that:

1. Pseudoephedrine products offered for sale are located either in an area where the public is not permitted or inside a locked display case; and
2. All distributions of pseudoephedrine products are conducted by an employee of the retailer. No pseudoephedrine products shall be dispensed by a self-service system of any kind.

37-3303. LIMITATIONS ON SALES AND PURCHASES.

1. It shall be unlawful for any retailer to knowingly sell, transfer or otherwise furnish in a single transaction a pseudoephedrine product or products containing more than nine (9) grams of pseudoephedrine.
2. It shall be unlawful for any person to knowingly purchase a pseudoephedrine product or products containing more than nine (9) grams of pseudoephedrine from a retailer in a single thirty (30) day period.
3. At the time of distribution or sale of a pseudoephedrine product or products, the retailer shall ensure that the purchaser presents a government-issued photo identification.

37-3304 PENALTIES. A person who knowingly violates any provision of this chapter shall be guilty of a misdemeanor.

37-3305. PREEMPTION. The provisions of this chapter shall be construed to preempt more stringent regulation of retail sales of pseudoephedrine products by any county, city or other political subdivision.

37-3306. APPLICATION. The provisions of this chapter shall not apply to a pseudoephedrine product dispensed pursuant to a valid prescription unless otherwise provided by law.

The Patriot Act

President George W. Bush signed legislation making the USA PATRIOT Improvement and Reauthorization Act of 2005 law. This federal law also addresses the sale and control of non-prescription medicines containing pseudoephedrine, ephedrine, and phenylpropanolamine and where it is more restrictive preempts state law. The following are the dates for the implementation of this act.

April 8, 2006 – limits how much one person can purchase to nine (9) grams in a 30-day period and 3.6 grams in a single day. Mail order is limited to sales of 7.5 grams in 30 days.

September 30, 2006 – Purchaser must present an identification (ID) card that provides a photograph and is issued by a state or the federal government, or a document that, with respect to ID, is considered acceptable as noted in the Code of Federal Regulations. The purchaser signs a logbook and enters his or her name, address, and the date and time of the sale and the seller determines that the name entered in the logbook corresponds to the name provided on such ID and that the date and time entered are correct and enters in the logbook the name of the product and the quantity sold. The seller maintains each entry in the logbook for not fewer than two years after the date on which the entry is made.

House Bill 611

HB 611 adds language that further clarifies what constitutes the validity of a prescription drug order.

54-1733. Validity Of Prescription Drug Orders

1. A prescription or drug order for a legend drug is not valid unless it is issued for a legitimate medical purpose <u>arising from a prescriber-patient relationship which includes a documented patient history and physical evaluation adequate to establish diagnoses and identify underlying conditions and/or contraindications to the treatment. Treatment, including issuing a prescription or drug order, based solely on an online questionnaire or consultation outside of an on-going clinical relationship does not constitute a legitimate medical purpose. A prescription or drug order may be issued either:</u>
   a. By a practitioner acting in the usual course of his profession; or
   b. By a physician, dentist, veterinarian, scientific investigator or other person, other than a pharmacist, who is licensed in a jurisdiction other than the state of Idaho and is permitted by such license to dispense, conduct research with respect to or administer the prescribed legend drugs in the course of his professional practice or research in such jurisdiction, so long as the individual is acting within the jurisdiction,

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FDA Cautions Consumers About Filling US Prescriptions Abroad

Food and Drug Administration (FDA) issued a warning to health care professionals and consumers that filling their prescriptions abroad may have adverse health consequences due to the confusion with drug brand names that could inadvertently lead consumers to take the wrong medication for their condition. In an investigation, FDA has found that many foreign medications, although marketed under the same or similar-sounding brand names as those in the United States, contain different active ingredients than in the US. Taking a different active ingredient could potentially harm the user.

FDA found 105 US brand names that have foreign counterparts that look or sound so similar that consumers who fill such prescriptions abroad may receive a drug with the wrong active ingredient. For example, in the United Kingdom, Amyben®, a brand name for a drug product containing amiodarone, used to treat abnormal heart rhythms, could be mistaken for Ambien®, a US brand name for a sedative. Using Amyben instead of Ambien could have a serious adverse outcome. For more information on this topic visit www.fda.gov/oc/opacom/reports/confusingnames.html.

Safety Can Not be Sacrificed For Speed

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Problem: Typically, pharmacies have developed well-established methods for monitoring the accuracy of the dispensing process. But today, pharmacy work is increasingly stressful and these checks and balances can easily be strained beyond capacity. With an increasing number of prescriptions and a shortage of qualified pharmacists, conditions are ripe for potentially unsafe working conditions – long hours without breaks; multitasking between answering phones, overseeing other pharmacy staff, dispensing prescriptions, and counseling patients; and ever-increasing time spent attending to insurance issues. Inevitably, these conditions can increase the chance for dispensing errors.

One pharmacy knows this all too well after a five-year-old boy died as a result of an order entry and medication compounding error that was not caught by the usual verification process. In this case, imipramine was dispensed in a concentration five times greater than prescribed. Imipramine is a tricyclic antidepressant used to treat adults, but it is also used to treat childhood enuresis. An extemporaneous solution was to be prepared at this pharmacy that specialized in compounded prescriptions since a liquid formulation was not commercially available. A pharmacy technician incorrectly entered the concentration of the prescribed solution into the computer as **50 mg/mL** instead of **50 mg/5 mL**, along with the prescribed directions to give 2 tsp at bedtime. He then proceeded to prepare the solution using the incorrect concentration on the label rather than the concentration indicated on the prescription. When the compound was completed, the technician placed it in a holding area to await a pharmacist's verification. At this time, one of the two pharmacists on duty was at lunch and the high workload of the pharmacy made it difficult for the pharmacist to check the prescription right away. When the child's mother returned to pick up the prescription, the cash register clerk retrieved the prescription from the holding area without telling a pharmacist, and gave it to the mother, unaware that it had not yet been checked. At bedtime, the mother administered 2 tsp of the drug (500 mg instead of the intended 100 mg) to the child. When she went to wake him the next morning, the child was dead. An autopsy confirmed imipramine poisoning.

There are many factors that contributed to this error including inaccurate order entry and issues related to high workload. However, a critical breakdown in safety processes occurred when the cash register clerk took the prescription from the pharmacy holding area (to prevent the mother from waiting any longer for the prescription), thereby circumventing the usual pharmacist verification process.

While this error underscores a growing problem in health care, the problem was clearly evident to this pharmacy owner – even a year before the error occurred. When interviewed for an article that appeared in a national publication, he vented his frustrations about the scant attention paid in our society to pharmacist workload difficulties faced in today's health care environment. On the day of the interview, 49 prescriptions were in the process of being prepared and about a dozen patients were standing in line or wandering around the store waiting for prescriptions. Yet this was a slow day. The owner also said that, while managed care had reduced profits considerably over the past several years, prescription volume had increased 50% (at the time of the error, the pharmacy was dispensing about 10,000 prescriptions per month versus 7,000 per month during the prior year, without an increase in staff) and medication regimens and drug interactions were more complex. To overcome these barriers, the owner added private consultation areas for patient counseling; installed a $175,000 robot that accurately dispenses the 200 most common drugs; and diversified sales to offset full-time pharmacists' salaries. But these efforts could not have prevented this tragic fatal error that circumvented the normal safety processes.

Safe Practice Recommendations: The environment and demands placed on health professionals significantly affect their ability to provide safe health care services. While technology such as robots can help, overstressed professionals cannot consistently perform at the maximum level of safety. Therefore, it is important that the public and health care leadership understand this problem so they can be more open to tradeoffs, such as working

with one patient at a time and incurring longer turnaround times, which are necessary to enhance patient safety. With a shortage of qualified professionals, we need to demand more rapid adoption of computerized prescribing to reduce time spent with prescription transcription. We should identify the biggest distractions that occur in our workplaces and eliminate or reduce the source by batching common interruptions and reorganizing work areas. Staff members need to be properly trained to understand safety procedures that are in place and know the limits of their specific duties. Fail-safe processes to ensure an independent double check before dispensing medications and performing other critical processes are a must. The pharmacy where this error occurred now requires two pharmacists to check every prescription. Unfortunately, this level of vigilance is typical after a patient has been harmed from an error. In other pharmacies, especially where there is only one pharmacist on duty, technicians may be involved in the double-check process.

A few other strategies can be used to prevent similar errors:

- Have one person perform order entry and a different person prepare the prescription, if possible, to add an independent validation of the order entry process.
- Do not prepare prescriptions using only the computer-generated label, as order entry may have been incorrect.
- Ensure that the original prescription, computer-generated label, prepared product, and manufacturer's product(s) remain together throughout the preparation process.
- Verify dispensing accuracy by comparing the original prescription with the labeled patient product and the manufacturer's product(s) used.

NIH Develops Community Drug Alert Bulletin

The National Institute on Drug Abuse, as part of the National Institutes of Health (NIH), has developed a new Community Drug Alert Bulletin that addresses the latest scientific research on the non-medical use of prescription drugs of abuse and addiction.

This bulletin is geared toward parents, teachers, counselors, school nurses, and health professionals who are associated with those at risk from prescription drug abuse for non-medical purposes. It summarizes the growing problem in the US and the trend of non-medical use of prescription drugs. For more information on this bulletin visit www.nida.nih.gov/PrescripAlert/index.html.

Implementation of the Anabolic Steroid Control Act of 2004

According to the December 16, 2005 *Federal Register*, effective January 20, 2005, the Anabolic Steroid Control Act of 2004 amended the Controlled Substances Act (CSA) and replaced the existing definition of "anabolic steroid" with a new definition. This new definition changed the basis for all future administrative scheduling actions relating to the control of the anabolic steroids as Schedule III controlled substances (CS) by eliminating the requirement to prove muscle growth. Also, the Act lists 59 substances as being anabolic steroids; these substances and their salts, esters, and ethers are Schedule III CS. The Act also revised the language of the CSA requiring exclusion of certain over-the-counter products from regulation as CS.

According to the House Report, the purpose of the Act is "to prevent the abuse of steroids by professional athletes. It will also address the widespread use of steroids and steroid precursors by college, high school, and even middle school students."

The changes to the definition include the following:

- Correction of the listing of steroid names resulting from the passage of the Anabolic Steroid Control Act of 1990.
- Replacement of the list of 23 steroids with a list of 59 steroids, including both intrinsically active steroids as well as steroid metabolic precursors.
- Automatic scheduling of the salts, esters, and ethers of Schedule III anabolic steroids without the need to prove that these salts, esters, or ethers promote muscle growth.
- Removal of the automatic scheduling of isomers of steroids listed as Schedule III anabolic steroids.
- Addition of dehydroepiandrosterone to the list of excluded substances.

FDA Unveils New Package Insert Format

On January 18, 2006, FDA unveiled a major revision to the format of prescription drug information, commonly called the package insert, which will give health care professionals clear and concise prescribing information. This new format was developed in order to manage the risks of medication use and reduce medical errors; the new package insert will provide the most up-to-date information in an easy-to-read format. This new format will also make prescription information more accessible for use with electronic prescribing tools and other electronic information resources.

Revised for the first time in more than 25 years, the new format requires that the prescription information for new and recently approved products meet specific graphical requirements and includes the reorganization of critical information so physicians can find the information they need quickly. Some of the more important changes include:

- A new section called *Highlights* to provide immediate access to the most important prescribing information about benefits and risks.
- A table of contents for easy reference to detailed safety and efficacy information.
- The date of initial product approval, making it easier to determine how long a product has been on the market.
- A toll-free number and Internet reporting information for suspected adverse events to encourage more widespread reporting of suspected side effects.

This new format will be integrated into FDA's other e-Health initiatives and standards-settings through a variety of ongoing initiatives at FDA. For more information please visit www.fda.gov/cder/regulatory/physLabel/default.htm.

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scope and authority of his license when issuing the prescription or drug order.

2. It is unlawful for practitioner to knowingly issue an invalid prescription or drug order for a legend drug.
3. It is unlawful for a pharmacist or veterinarian to knowingly fill an invalid prescription or drug order for a legend drug.

Medisets

There is still confusion surrounding medisets and similar delivery systems that are being labeled by the pharmacist for use in assisted living and residential care facilities or for private individuals. The most recent issue before the Board regarding the mediset systems required an official interpretation to standardize the definition of a mediset. The Board determined that in order for a mediset container to be correctly labeled, the immediate container the medication is dispensed in must be a solid container that is not conducive to separation. Proper labeling of the mediset container or similar delivery systems is another area causing some confusion. A mediset or similar delivery system is required to meet all requirements of IDAPA 27.01.01.0159.02 for prescription labels. At a minimum all medisets shall bear a label containing the name, address, and phone number of the dispenser; the serial number and date of each prescription; name of the prescriber; name of the patient; directions for use; name of the medication (including manufacturer's name if a generic); any cautionary statements, including, when advisable, the manufacturer's original expiration date; quantity of the item dispensed; the initials of the person dispensing; and the statement: "Warning: Federal and State law prohibits the transfer of this prescription to any person other than the person for whom it was prescribed."

MedGuides Are Piling Up on Many Pharmacy Counters

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There are now more than 30 MedGuides . . . with more on the way. For example, a MedGuide is required for **all** antidepressants and [non-steroidal anti-inflammatory drugs] NSAIDs . . . even OTC [over-the-counter] NSAIDs if you dispense them as a prescription. The new inhaled insulin, *Exubera®,* will come with a 15-page MedGuide about its effects on the lungs and proper use of the inhaler. There's talk about a MedGuide for ADHD [attention deficit hyperactivity disorder] stimulants (*Adderall®*, *Ritalin®*, etc) . . . to warn about cardiac and psychiatric effects. The FDA [Food and Drug Administration] requirement applies whenever a "MedGuide drug" is given for outpatient use . . . from a community pharmacy or upon hospital discharge. They are required for both new **and** refill Rxs [prescriptions], but many pharmacists admit that they're not doing it. Legally speaking, that's dangerous. It's like dispensing a mislabeled drug. The MedGuide is part of the labeling and failure to dispense it is a violation. Legal experts and state boards suggest having a system in place to help ensure MedGuides are given out. Encourage your pharmacy computer programmers to give you an alert anytime you're dispensing a MedGuide drug. Consider putting reminders on the shelf . . . or enter an asterisk next to the drug name in the computer. Explain to your technicians the importance of giving a MedGuide. Keep in mind you **can** omit the MedGuide if the prescriber requests . . . but be sure to document that. However, patients can override. If the patient asks for a MedGuide, you must give it. Be familiar with each MedGuide, and counsel patients as needed. You can help put the information in perspective and prevent it from scaring patients out of taking their meds. We've set up an online system that allows you to print any MedGuide, anytime you need. Go to our Detail-Document for a link to each MedGuide. **Detail-Document #220331**

Boxed Warnings

Boxed warnings, also called "Black Box" warnings, are prominently displayed summaries of serious adverse reactions and potential safety hazards for a drug product in its prescribing information as required by FDA. These boxed warnings are the most serious of warnings for a drug. "Black Box" products can present significant risk for patients and require informed patient consent prior to prescription. A boxed warning is warranted when a drug presents a unique risk to benefit concern compared with other drugs in the same class, when a potential adverse reaction is extremely significant above the drug's benefit, and when such adverse reactions can be prevented or reduced by restricted use or observance of defined cautions. Often boxed warnings are based on observed adverse reactions but they can also be based on animal toxicity or expected adverse reactions. These boxed warnings are described in the FDA, Center for Devices and Radiological Health, Code of Federal Regulations [21CFR 201.57(e)]. It is required that prescribers provide patients with information on treatment risks, benefits, and warnings as part of the patient's right of informed consent. Some practitioners document this in the patient's chart.

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